EMA/583690/2010

European Medicines Agency decision

P/183/2010

of 24 September 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral for (Glycinamide, L-cysteinyl-L-phenylalanyl-L-isoleucyl-6-oxo-L-lysyl-L-asparaginyl-L-cysteinyl-L-prolyl-N5-(1-methylethyl)-L-ornithyl-, cyclic(1→6)-disulfide acetate) (FE 202158 acetate) (EMEA-000506-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This Decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8670
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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on the agreement of a paediatric investigation plan and on the granting of a deferral for (Glycinamide, L-cysteinyl-L-phenylalanyl-L-isoleucyl-6-oxo-L-lysyl-L-asparaginyl-L-cysteinyl-L-prolyl-N5-(1-methylethyl)-L-ornithyl-, cyclic(1→6)-disulfide acetate) (FE 202158 acetate) (EMEA-000506-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the application submitted by International Pharma Science Center, Ferring Pharmaceuticals A/S on 30 January 2009 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 6 August 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a paediatric investigation plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for (Glycinamide, L-cysteinyl-L-phenylalanyl-L-isoleucyl-6-oxo-L-lysyl-L-asparaginyl-L-cysteinyl-L-prolyl-N5-(1-methylethyl)-L-ornithyl-, cyclic(1 → 6)-disulfide acetate) (FE 202158 acetate), concentrate for solution for infusion, intravenous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for (Glycinamide, L-cysteinyl-L-phenylalanyl-L-isoleucyl-6-oxo-L-lysyl-L-asparaginyl-L-cysteinyl-L-prolyl-N5-(1-methylethyl)-L-ornithyl-, cyclic(1→6)-disulfide acetate) (FE 202158 acetate), concentrate for solution for infusion, intravenous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to International PharmaScience Center, Ferring Pharmaceuticals A/S, Kay Fiskers Plads 11, 2300 Copenhagen, Denmark.

Done at London, 24 September 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/482339/2010

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMEA-000506-PIP01-08

Scope of the application

Active substance(s):

(Glycinamide, L-cysteinyl-L-phenylalanyl-L-isoleucyl-6-oxo-L-lysyl-L-asparaginyl-L-cysteinyl-L-prolyl-N5-(1-methylethyl)-L-ornithyl-, cyclic(1→6)-disulfide acetate) (FE 202158 acetate)

Condition(s):

Treatment of septic shock

Pharmaceutical form(s):

Concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

International Pharma Science Center, Ferring Pharmaceuticals A/S

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, International Pharma Science Center, Ferring Pharmaceuticals A/S submitted for agreement to the European Medicines Agency on 30 January 2009 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 25 June 2009.

Supplementary information was provided by the applicant on 21 May 2010.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
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E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
   - to grant a deferral in accordance with Article 21 of said Regulation.

   The Norwegian Paediatric Committee member(s) agree(s) with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex(es) and appendix.

London, 6 August 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

The measures and timelines of the agreed Paediatric Investigation Plan

1. Condition(s)

Treatment of septic shock

2. Waiver

Not applicable

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Treatment of septic shock

3.1.1. Indication(s) targeted by the PIP

Treatment of septic shock in paediatric patients in need of vasopressor support

3.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age.

3.1.3. Pharmaceutical form(s)

Concentrate for solution for infusion

3.1.4. Studies

Area	Number of studies	Description
Quality	2	1. Development of a concentrate for solution for infusion suitable for use in neonates and infants and avoiding the need for multiple manipulation/dilution steps. 2. Study of potential interactions/compatibility issues of FE 202158 with the most commonly co-administered IV medications and infusions used in the paediatric population
Non-clinical	4	3. Dose range finding, kinetic and tolerance study by 24 hour iv infusion in juvenile dogs 4. Four week toxicity study by 24 hour iv infusion in juvenile dogs 5. Toxicity study in juvenile dogs (PND 4) 6. Pharmacodynamic study in an animal model of neonatal septic shock
Clinical	3	7. Pharmacokinetic study of FE 202158 in children aged 1 – 12 years with warm septic shock 8. Safety, tolerability and efficacy study evaluating two doses of FE

		202158 for vasopressor support in children aged 1 – 18 years with warm septic shock 9. Safety, tolerability and efficacy study of ascending doses of FE 202158 for vasopressor support in children aged 0 – 1 year including pre-terms with warm septic shock

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues or of efficacy in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By September 2023
Deferral for one or more studies contained in the paediatric investigation plan:	Yes